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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/046,840	03/24/1998	DAKAI LIU	ENZ-56(DIV3)	2602

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ENZO THERAPEUTICS, INC.  
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NEW YORK, NY 10022

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/046,840

Applicant(s)

LIU ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 68-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 68-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **Detailed Action**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 68 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmons et al.

Applicants claim a first vector which can be a viral nucleic acid wherein said first vector is capable of producing a second vector (of a different chemical nature) in a packaging cell wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter(s), terminator sequences, enhancers, etc.

Salmons et al. (Human Gene Therapy, Vol. 4, 1993, pp. 129-141, see whole article, particularly Fig. 3 and pages 133-135) recites a first retroviral vector (i.e. a retroviral DNA provirus) wherein said vector (in the packaging cell) is capable of producing a second vector (of a different chemical nature, retroviral single stranded (partially) RNA genome) in a packaging cell line wherein the second vector is capable of expressing an exogenous gene in a target cell and said vector contains a promoter, terminator sequences, etc. Therefore, Salmons et al. teaches the claimed invention.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designating the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68, 70, 73 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al.

Applicants and Wilson et al. (U.S. Patent 5,856,152, issued 1/5/99, filed 10/28/94, see whole document, particularly Columns 8-9 (Section entitled "Regulatory Elements of the Hybrid Vector", Column 12 and Claims 1-2) recite a first viral vector (Wilson et al. recites a AAV/Ad vector) which when introduced into a packaging cell produces a second vector (Wilson et al. recites a AAV vector produced from (rescued) from the AAV/Ad vector) wherein the packaging cell provides the AAV packaging components and wherein the second vector is structurally different (in size) from the first vector and can comprises a promoter, enhancer, termination sequences, integration segment, etc. Wilson et al. therefore teaches the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 (and dependent claims) are vague in the recitation of the phrase "...is produces a second vector...".

Claims 71, 72 and 74 are vague in the recitation of the phrase "...of said group." because there are multiple groups recited in claims 70 and 68 and it is unclear which group is being referred to.

Claims 71, 72 and 74 are vague in the recitation of the phrase "...the (I) viral nucleic acid or (emphasis added) the (iii) nucleic acid construct comprises a different member of said group." because it is unclear what type of comparison is being made here, i.e. each member is different from what standard?

Claim 74 is vague because it is unclear if applicants mean to recite vectors or nucleic acids comprising **all** of the recited components (promoters, enhancers, integration segment and terminator) together or in the alternative because applicants also recite in the claim "or a combination of any" of the aforementioned components.

Claim 73 is vague in that the claim can be read to recite "said nucleic acid size...comprises a

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segment" of nucleic acid. The term "nucleic acid size" is not a composition which can comprise anything, it is rather a description of the nucleic acid.

Claim 78 is vague in that it is unclear what applicants mean by a cell line which is "native" to a viral vector, since a viral vector can contain portions of different viruses, each with their own "native" cell lines. It is also unclear what applicants mean by the term "native", i.e. a cell which can support replication of the virus or a cell which can be infected by the virus but not produce progeny virions, etc.?

Any rejections not repeated in this Office Action are withdrawn.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014. Also, faxes may be sent directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
November 25, 2002

DAVID GUZO  
PRIMARY EXAMINER  
*David Guzo*